

REMARKS

This paper is intended to be a complete response to the above-identified Office Action. It is believed no fee is due. If fees are required, however, the Commissioner is authorized to deduct the necessary charges from Deposit Account 501927/010-US-002.

Claims 13 and 25 have been amended. Claim 12 has been cancelled without prejudice. Accordingly, claims 1-4, 10, 11, 13-31, 33 and 34 are currently pending in the instant patent application.

Section 112, Paragraph 2, Rejections

The Examiner has rejected claims 1-4, 10-31, 33 and 34 under 35 U.S.C. 112, second paragraph, as allegedly failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Specifically the Examiner asserts that (see Office Action at pages 2-4):

Independent claim 1 is vague and indefinite for reciting "a light source adapted to illuminate," "a detector adapted to detect" and further for reciting, "cytometric characteristic of a sample." Dependent claim 2 are vague and indefinite for reciting "a bar code adapted to be interrogated. Dependent claims 3 and 4 are vague and indefinite because it is "unclear what comprises the calibration standards and how it structurally relates to the claimed apparatus so as to perform its function as a calibration standard since it does not appear to assist in sorting cells as in the photoactivated linker."

Independent claim 10 is rejected for similar reasons with respect to use of the phrase "a light source adapted to illuminate." Dependent claims 11-13, 23, 26 and 27 are vague and indefinite for various reasons analogous to those recited against independent claims 1 and 10.

The Examiner's assertion that Assignee's "adapted to" language is vague and indefinite is, in light of the specification and established patent office procedure, without merit. Specifically, the "adapted to" language as employed herein has been explicitly acknowledged and accepted for use in claims. See M.P.E.P. 2173.05(g), *citing In re*

Venezia, 530 F.2d 956 (CCPA 1976). As further evidence of the widespread, accepted and non-vague nature of this claim language, a search of the U.S. Patent database reveals that in the last five (5) years alone, more than 890 issued patents directed to centrifugation methods and apparatus that include the "adapted to" language.¹ By way of example only, the Examiner is directed to the following *issued* patents: **(1)** 6,382,228 – claim 5 is directed to a fluid driving system for portable flow cytometers "... wherein the plunger is adapted to be manually depressed into the first pressure chamber;" **(2)** 6,372,506 – claim 1 is directed to an "apparatus, for use in a flow cytometer ... comprising: a first detector, adapted to detect;" **(3)** 6,159,748 – claim 3 is directed to a "non-agglutination, sandwich anti-SLE test kit for use with a flow cytometer ... comprising ... a wash concentrate adapted to be converted to a wash solution by adding a quantity of distilled water;" **(4)** 5,915,925 – claim 2 is directed to an "apparatus for providing a consistent liquid pressure output ... comprising ... an accumulator means. wherein the accumulator is adapted for connection to a flow cytometer;" **(5)** 6,572,450 -- claim 1 is directed to an "apparatus for processing optical components, comprising ... a polishing material supply apparatus adapted to supply a web of polishing material;" **(6)** 6,572,040 -- claim 10 is directed to a "coal processing mill ... wherein the ash removing means comprises ... a valve adapted to eject the peptized, clay-carrying fluid ... [and a] ... barrier being adapted to block the insoluble, more dense mineral ash particles"; **(7)** 6,573,088 -- claim 1 is directed to a "random access microbiological analyzer ... comprising ... a pipetting apparatus adapted to aspirate patient sample and ... also adapted to dispense an amount of patient sample;" **(8)** 6,572,524 -- claim 8 is directed to a decanter centrifuge "for separating a heavy phase material from a liquid within a feed mixture ... comprising ... (c) a disc ... adapted to project into the separated heavy phase material being conveyed;" **(9)** 6,471,855 (claim 35 is directed to a "disposable blood separation set ... comprising ... a drive

1. A search for the terms "adapted to" and "centrifugat!" appearing in the claims of utility patents issued during the past five (5) years identified 893 patents. This search was performed using the Lexis/Nexis research system on 9 June 2003 by the below signed attorney.

member adapted to be magnetically coupled to actuator device;" and **(10)** 6,464,624 (claim 18 is directed to an apparatus "for processing blood to separate and collect a selected lower density component thereof from other higher density components of the blood ... comprising ... a rotary chuck and adapted for rotation about an axis."

Assignee declines to amend dependent claims 3 and 4 and, further, does not understand Examiner's rejection thereof. It appears the Examiner "links" dependent claims 3 and 4 together. No such linkage exists. Claim 3 depends from claim 1 and claim 4 depends from claim 1. There is no need, physically or legally, for the calibration standard of claim 3 to be related to the photoactivated cross-linker of claim 4. It is further noted that the specification, at page 8 (Example 10), explicitly describes one embodiment of a calibration standard. Further, Assignee declines to amend independent claims 1 and 10 with respect to the phrase "cytometric characteristic" as this phrase, especially in light of the specification, would be clear to anyone having ordinary skill in the art of cytometry (see prior discussion).

Accordingly, the language of claims 1-4, 10-31, 33 and 34 satisfies the statutory requirement that they particularly point out and distinctly claim the subject matter which the applicant regards as his invention as to one of ordinary skill in the art. 35 U.S.C. 112, paragraph 1. Assignee respectfully requests the Examiner withdraw these rejections and allow claims 1-4, 10-31, 33 and 34 to pass to issue.

Section 112, Paragraph 1, Rejection

The Examiner has rejected claim 12 under 35 U.S.C. 112, first paragraph, as allegedly "containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." (See Office Action at page 4-5.)

For reasons cited in Assignee's prior Reply, the Examiner is believed to be mistaken. However, to speed this application to issuance, Assignee has cancelled claim

12 in the instant application without prejudice to its continued prosecution in a continuation application.

Section 103 Rejections: Cottingham and Walters

The Examiner has rejected claims 1, 3, 4, 10-18, 22, 24-31, 33 and 34 as allegedly being unpatentable under 35 U.S.C. 103(a) over Cottingham (U.S. Patent 5,639,428) in view of Walters (U.S. Patent 6,135,940). (See Office Action at pages 5-7.)

As noted in Assignee's prior Reply, neither Cottingham or Walters teach, describe or *fairly suggest* the invention of independent claims 1 and 10. Cottingham does not teach or suggest any rotation of a sample vial about its longitudinal axis or the simultaneous rotation and interrogation of the sample vial via a light source. Walters teaches the incremental (discrete) rotation of a sample vial which is held stationary with respect to the detector during interrogation.

Neither Cottingham or Walters teach, describe or fairly suggest that the discrete rotation and fixed interrogation scheme of Walters be combined with the centrifuging rotation of Cottingham. "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." M.P.E.P. 2143.01 quoting *In re Mills*, 916 F.2d 680, 682 (Fed. Cir. 1990). Further, a "statement that modifications of the prior art to meet the claimed invention would have been 'well within the ordinary skill of the art at the time the claimed invention was made' because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a prima facie case of obviousness without some objective reason to combine the teachings of the references." M.P.E.P. 2143.01 quoting *Ex parte Levengood*, 28 U.S.P.Q.2d (BNA) 1300 (Bd. Pat. App. & Inter. 1993).

Accordingly, the Examiners use of Cottingham and Walters to reject claims 1, 3, 4, 10-18, 22, 24-31, 33 and 34 is improper. Assignee respectfully requests this rejection be withdrawn and the claims allowed to pass to issue.

Section 103 Rejections: Anderson and Walters

The Examiner has rejected claims 1, 4, 10, 13-18, 22, 26-29, 31, 33 and 34 as allegedly being unpatentable under 35 U.S.C. 103(a) over U.S. Patent 6,254,834 to Anderson et al. (hereinafter Anderson) in view of Walters. (See Office Action at pages 8-9.)

Anderson appears to be directed to a "method for separating microorganisms ... from a mixture by two dimensional centrifugation." (In Anderson, see Abstract and col. 7, lines 31-38.) Anderson appears to specifically describe special centrifugation tubes (see col. 7, line 65 to col. 8, lines 4) in which a sample is deposited along with separation disks (see col. 8, lines 42-45) and which are then spun (see col. 9, lines 7-11). Of particular relevance, the tubes and associated methods and apparatus of Anderson **(1)** do not spin about their longitudinal axis (see col. 9, lines 34-40) and **(2)** moved into a fixed position prior to examination (see col. 10, lines 22-28 and FIG. 5; col. 10, lines 46-49 and FIG. 6; and col. 11, lines 32-37 and FIG. 7).

Neither Anderson or Walters teach, describe or fairly suggest that the discrete rotation and fixed interrogation scheme of Walters be combined with the centrifuging motion and fixed position interrogation scheme of Anderson. Again, the Examiner appears to be relying on hindsight reconstruction (for the motivation to combine) rather than on the cited prior art. Such reliance is strictly forbidden by established case law and Patent Office procedure. See M.P.E.P. 2143.01, *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308 (Fed. Cir. 1999); *In re Bond*, 910 F.2d 831, 834 (Fed. Cir. 1986); *In re Stencel*, 828 F.2d 751, 755 (Fed. Cir. 1987); and *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577 (Fed. Cir. 1987).

For at least the same legal reasons cited above with respect to the combination of Cottingham and Walters, the Examiners use of Anderson and Walters to reject claims 1, 4, 10, 13-18, 22, 26-29, 31, 33 and 34 is improper. Assignee respectfully requests this rejection be withdrawn and the claims allowed to pass to issue.

Section 103 Rejections: Cottingham, Anderson, Walters and Surmodics, Inc.

The Examiner has rejected claims 19, 20 and 23 as allegedly being unpatentable under 35 U.S.C. 103(a) over Nottingham or Anderson in view of Walters and further in view of Surmodics, Inc. (See Office Action at pages 9-11.)

Each of claims 19, 20 and 23 depend from independent claim 10. Because independent claim 10 is allowable over the cited prior art as discussed above, each of dependent claims 19, 20 and 23 is allowable. Assignee respectfully requests this rejection be withdrawn and the claims allowed to pass to issue.

Section 103 Rejections: Cottingham, Anderson, Walters

The Examiner has rejected claims 2 and 21 as allegedly being unpatentable under 35 U.S.C. 103(a) over Nottingham or Anderson in view of Walters. (See Office Action at pages 11-12.)

Claim 2 depends from independent claim 1 and claim 21 depends from independent claim 10. Because independent claims 1 and 10 are allowable over the cited prior art as discussed above, each of dependent claims 2 and 21 is allowable. Assignee respectfully requests this rejection be withdrawn and the claims allowed to pass to issue.

CONCLUSIONS

Reconsideration of the pending claims 1-4, 10, 11, 13-31, 33 and 34, in light of the above remarks and amendments is respectfully requested. If, after considering this reply, the Examiner believes that a telephone conference would be beneficial towards advancing this case to allowance, the Examiner is strongly encouraged to contact the undersigned attorney at the number listed.



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